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| 10/565,009   | 01/18/2006  | Anne-Marie Pinel     | 34930157PUS1                    | 7178                        |
| 2292 7590 06/28/2007<br>BIRCH STEWART KOLASCH & BIRCH<br>PO BOX 747<br>FALLS CHURCH, VA 22040-0747 |             |                      | EXAMINER<br>HA, JULIE           |                             |
|  |             |                      | ART UNIT<br>1654                | PAPER NUMBER                |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

**Office Action Summary**

Application No.

10/565,009

Applicant(s)

PINEL ET AL.

Examiner

Julie Ha

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 8 and 11-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8 and 11-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Response to Election/Restriction filed on May 24, 2007 is acknowledged. Claims 1-6, 8 and 11-16 are pending in this application.

#### ***Election/Restriction***

1. Applicant's election with traverse of species Acetyl-Arg-Lys-Asp-Val-HomoPhe-NH<sub>2</sub> for the first peptide, Acetyl-Lys-Gly-His-Lys-NH<sub>2</sub> for the second peptide, 5-alpha-reductase inhibitors for compound that improves hair growth, and triazines for the UVB filter in the reply filed on May 24, 2007 is acknowledged. The traversal is on the ground(s) that all the peptides employed in the embodiments share the sequence "Lys-Asp-Val" and all of these peptides are relatively small. Second, the variables "A", "W", and "Z" are also small in scope, such that the search and examination of all of these related embodiments places no undue burden on the Examiner. This is not found persuasive because independent searches would have to be conducted on the peptide sequences. For example, a search for A-Glu-Gln-Arg-Lys-Asp-Val-Tyr-Val-Gln-Leu-Tyr-NH<sub>2</sub> would not necessarily lead to the peptide sequence A-Gly-Gln-Gln-Lys-Asp-Val-Leu-DOPA. Furthermore, the structures of the peptides are patentably independent and distinct due to different amino acid contents.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-6, 8 and 11-16 are examined on the merits in this office action.

***Objection-Minor Informalities***

2. The title is objected to because the title is too long. The title is limited to 2-7 words maximum. Furthermore, the use of the word "Novel" is objected to since the Patent Office will determine what is "Novel" and what is not. A new title is required that is clearly indicative of the invention to which the claims are directed.

3. The specification is objected to for the following reasons:

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

**Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

***Rejection-35 U.S.C. 112, 1<sup>st</sup>***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-6, 8 and 11-16 are rejected are under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature or the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

*(1) The nature of the invention:*

The invention is drawn to a method of preventive and curative treatment of alopecia comprising the administration of an effective amount of a peptide or peptide conjugate. Furthermore, the invention is drawn to a cosmetic treatment method to combat hair loss that includes the application on the scalp of a compound comprising a peptide or a peptide conjugate (see paragraph [0044]).

*(2) The state of the prior art:*

The Merck manual indicates that alopecia has multiple causes and treatment is of underlying causes (see Merck manual, Alopecia, 1<sup>st</sup> and 2<sup>nd</sup> sentences). The Merck manual indicates that alopecia can be nonscarring and diffuse, nonscarring and focal, or scarring and focal. Nonscarring diffuse loss includes male-pattern baldness, female-pattern baldness, telogen effluvium, anagene effluvium, primary hair shaft abnormalities and congenital disorder. Telogen effluvium is loss of scalp hair caused by synchronicity of hair cycle so that many hairs enter the resting or telogen phase at once (see Merck manual, p. 1 6<sup>th</sup> paragraph).

The Merck manual indicates that most treatments for hair loss have been developed for male-pattern baldness because it is so prevalent. The treatments include Minoxidil, which prolongs the anagen phase and may increase blood flow to the follicle...is generally not effective or indicated for other causes except possible alopecia areata. Hair growth may not be seen until 6 to 9 months, and a common practice is to continue treatment as long as positive results persist (see Merck manual, p. 3, 7<sup>th</sup>

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paragraph). The Merck manual indicates that Finasteride inhibits 5-alpha reductase enzyme, blocking conversion of testosterone to dihydrotestosterone, and is useful for male-pattern baldness. Hair growth may not be seen until 6 months, and common practice is to continue treatment for 24 months as long as positive results persist. Once treatment is discontinued, hair loss returns to previous level (see Merck manual, p. 3, 8<sup>th</sup> paragraph).

Leshin L, MD indicates that there is no cure at present for alopecia; treatment is currently aimed at helping hair regrowth, but it cannot stop the spread of hair loss (see p. 2, [www.ds-health.com/derm.htm](http://www.ds-health.com/derm.htm)). Further, WebMeds also indicates that there is no "cure" for baldness. Treatments are available, however, that help to slow hair loss and promote hair growth (see p. 2, [www.webmeds.us/hair-loss.html](http://www.webmeds.us/hair-loss.html)). Furthermore, Better Health Channel of the Australian government indicates that the most common cause of hair loss in men is androgenic alopecia, or male pattern baldness. While there are a number of treatments available for male pattern baldness, there is no cure. Treatments include minoxidil and finasteride medication (see top of p. 2, [betterhealthchannel.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Hair\\_loss?Open](http://betterhealthchannel.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Hair_loss?Open)). Additionally, the University of Pennsylvania Health System also indicates that there is no cure for hair loss caused by androgenetic alopecia, although treatments are available. Further, there is no cure for hair loss caused by alopecia areata, nor approved medications specifically targeted to cure this disease (see p. 1, [www.pennhealth.com/hairtransplant/types.html](http://www.pennhealth.com/hairtransplant/types.html)).

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The art provide guidance as how to alleviate hair loss and the treatment requires continuation of treatment and if treatment is discontinued, hair loss returns to previous levels. However, the art does not provide how to determine individuals who are susceptible to hair loss. The Merck manual indicates that there are many causes of hair-loss, and since the symptoms are often absent (and when present not specific to any cause), it would be hard to determine individuals susceptible to hair loss (alopecia). Additionally, many arts have indicated that there is no cure for alopecia; treatments are available that help to slow hair loss and promote hair growth. Prior art does not provide guidance as how to determine individuals who are susceptible to alopecia.

*(3) The relative skill of those in the art:*

The relative skill of those in the art is high.

*(4) The predictability or unpredictability of the art:*

Applicant's activity is based on the determination of predicting those who are susceptible to alopecia. Since the activity is based on determining the patient population that is susceptible to alopecia, the predictability in the art is low. This is due to the fact that the art has recognized the difficulty in determining the patient population who are susceptible to alopecia. For example, not all men have male-pattern baldness. Additionally, the Applicant discloses that the majority of cases are androgenic alopecia, due to a defect in the catabolism of androgens, more precisely of testosterone, at the level of the hair follicle, by the cells of dermal papilla (see paragraph [0006]). As



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described above, the Merck manual indicates that most treatments for hair loss have been developed for male-pattern baldness because it is so prevalent. The treatments include Minoxidil, which prolongs the anagen phase and may increase blood flow to the follicle...is generally not effective or indicated for other causes except possible alopecia areata. Hair growth may not be seen until 6 to 9 months, and a common practice is to continue treatment as long as positive results persist (see Merck manual, p. 3, 7<sup>th</sup> paragraph). The Merck manual indicates that Finasteride inhibits 5-alpha reductase enzyme, blocking conversion of testosterone to dihydrotestosterone, and is useful for male-pattern baldness. Hair growth may not be seen until 6 months, and common practice is to continue treatment for 24 months as long as positive results persist. Once treatment is discontinued, hair loss returns to previous level (see Merck manual, p. 3, 8<sup>th</sup> paragraph).

Leshin L, MD indicates that there is no cure at present for alopecia; treatment is currently aimed at helping hair regrowth, but it cannot stop the spread of hair loss (see p. 2, [www.ds-health.com/derm.htm](http://www.ds-health.com/derm.htm)). Further, WebMeds also indicates that there is no "cure" for baldness. Treatments are available, however, that help to slow hair loss and promote hair growth (see p. 2, [www.webmeds.us/hair-loss.html](http://www.webmeds.us/hair-loss.html)). Furthermore, Better Health Channel of the Australian government indicates that the most common cause of hair loss in men is androgenic alopecia, or male pattern baldness. While there are a number of treatments available for male pattern baldness, there is no cure. Treatments include minoxidil and finasteride medication (see top of p. 2, [betterhealthchannel.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Hair\\_loss?Open](http://betterhealthchannel.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Hair_loss?Open)).

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Additionally, the University of Pennsylvania Health System also indicates that there is no cure for hair loss caused by androgenetic alopecia, although treatments are available. Further, there is no cure for hair loss caused by alopecia areata, nor approved medications specifically targeted to cure this disease (see p. 1, [www.pennhealth.com/hairtransplant/types.html](http://www.pennhealth.com/hairtransplant/types.html)).

The art, however, does not provide guidance as how to prevent and cure alopecia altogether. The art indicates that there is no cure for alopecia. The claim doesn't identify the patient population, therefore, the claim implies that anyone can be protected against alopecia. However, the Applicant has not shown who will be susceptible to alopecia. There are too many variables between the patient populations, thus, it clearly shows the unpredictability of the art.

*(5) The breadth of the claims:*

The claim is drawn to a method of preventive and curative treatment of alopecia comprising the administration of an effective amount of a peptide or peptide conjugate. Although claims 1-6 and 11-16 are drawn to a cosmetic or pharmaceutical compound, they have been interpreted as useful for any one purpose. When discussing the use of the peptide, the specification only discloses the use of peptide as preventive and curative treatment of alopecia (see paragraph [0039]). The cosmetic treatment is also preventive and curative treatment because the specification discloses that "a cosmetic treatment method to combat hair loss". The term "combat" is an absolute definition which means to stop from occurring and, thus, means preventive and curative.

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Therefore, the term "cosmetic treatment method to combat hair loss" is interpreted as preventing and curing hair loss.

*(6) The amount of direction or guidance presented and (7) The presence or absence of working examples:*

Although the specification provides guidance on how to administer the compound, it is unclear as to when to administer the compound and the patient population. The specification discloses that the peptide or peptide conjugates can be administered for their cosmetic use via the topical route, in food supplements, via the oral route (see paragraphs [0037]-[0038]); the cosmetic or dermatological compound can be presented in the form of a lotion, a medicated shampoo, a spray, a gel, or a medicated cream (see paragraph [0042]). Furthermore, the specification discloses that the peptide or a peptide conjugate is for use as a medicine as well as for the preventive and curative treatment of alopecia (see paragraph [0039]) and a cosmetic treatment method to combat hair loss (see paragraph [0044]). The working examples disclose the ingredient of a lotion that includes the peptide conjugates Ac-Lys-Asp-Val-DOPA-NH<sub>2</sub> and Ac-Arg-Lys-Asp-Val-HomoPhe-NH<sub>2</sub> (see Examples 1 and 2). The specification however, fails to provide any working examples that established a cure or prevention of alopecia that can be achieved using the claimed peptides. Such examples are necessary since the art indicates that a cure and prevention of alopecia does not exist. For example, Leshin L, MD indicates that there is no cure at present for alopecia; treatment is currently aimed at helping hair regrowth, but it cannot stop the spread of

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hair loss (see p. 2, [www.ds-health.com/derm.htm](http://www.ds-health.com/derm.htm)). Further, WebMeds also indicates that there is no "cure" for baldness. Treatments are available, however, that help to slow hair loss and promote hair growth (see p. 2, [www.webmeds.us/hair-loss.html](http://www.webmeds.us/hair-loss.html)).

Furthermore, Better Health Channel of the Australian government indicates that the most common cause of hair loss in men is androgenic alopecia, or male pattern baldness. While there are a number of treatments available for male pattern baldness, there is no cure. Treatments include minoxidil and finasteride medication (see top of p. 2, [betterhealthchannel.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Hair\\_loss?Open](http://betterhealthchannel.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Hair_loss?Open)).

Additionally, the University of Pennsylvania Health System also indicates that there is no cure for hair loss caused by androgenetic alopecia, although treatments are available. Further, there is no cure for hair loss caused by alopecia areata, nor approved medications specifically targeted to cure this disease (see p. 1, [www.pennhealth.com/hairtransplant/types.html](http://www.pennhealth.com/hairtransplant/types.html)).

The specification has not provided guidance in the way of a disclosure to how to determine individuals that need protection against alopecia. The specification discloses that the invention is particularly suited to male patients having the majority case of androgenic alopecia (see paragraph [0006]). However, as indicated by the arts cited above, there are no cure for alopecia.

There is no clear guidance as to how to determine the patient population, since not all men suffer from male-pattern baldness or alopecia as described above. Since the prior art is still unclear as to who are susceptible to alopecia, more guidance is necessary.

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*(8) The quantity of experimentation necessary:*

Since it is uncertain to predict the patient population who are susceptible for alopecia, and the Applicant have not provided the appropriate time frame at which the compound should be administered, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine if the peptide or peptide conjugate would be effective in preventing or curing alopecia.

Please note that the terms "prevent" and "combat" and "cure" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "therapeutic" or "treat" or "alleviate", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes)- including preventing such disorders as alopecia, which is clearly not recognized in the medical art as being totally preventable condition.

***Rejection-35 U.S.C. 101***

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-6, 8 and 11-16 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. The MPEP states the following: An invention that is "inoperative" (i.e., it does not operate to produce the results claimed by the patent applicant) is not a "useful" invention in the meaning of the patent law. See, e.g., Newman v. Quigg, 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir.

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1989); In re Harwood, 390 F.2d 985, 989, 156 USPQ 673, 676 (CCPA 1968) ("An inoperative invention, of course, does not satisfy the requirement of 35 U.S.C. 101 that an invention be useful."). However, as the Federal Circuit has stated, "[t]o violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1571, 24 USPQ2d 1401, 1412 (Fed. Cir. 1992) (emphasis added). See also E.I. du Pont De Nemours and Co. v. Berkley and Co., 620 F.2d 1247, 1260 n.17, 205 USPQ 1, 10 n.17 (8th Cir. 1980) ("A small degree of utility is sufficient . . . The claimed invention must only be capable of performing some beneficial function . . . An invention does not lack utility merely because the particular embodiment disclosed in the patent lacks perfection or performs crudely . . . A commercially successful product is not required . . . Nor is it essential that the invention accomplish all its intended functions . . . or operate under all conditions . . . partial success being sufficient to demonstrate patentable utility... In short, the defense of non-utility cannot be sustained without proof of total incapacity." If an invention is only partially successful in achieving a useful result, a rejection of the claimed invention as a whole based on a lack of utility is not appropriate. See In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995); In re Gardner, 475 F.2d 1389, 177 USPQ 396 (CCPA), reh 'g denied, 480 F.2d 879 (CCPA 1973); In re Marzocchi, 439 F.2d 220, 169 USPQ 367 (CCPA 1971). One situation where an assertion of utility would not be considered credible is where a person of ordinary skill would consider the assertion to be "incredible in view of contemporary knowledge" and where nothing offered by the applicant would counter

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what contemporary knowledge might otherwise suggest. Office personnel should be careful, however, not to label certain types of inventions as “incredible” or “speculative” as such labels do not provide the correct focus for the evaluation of an assertion of utility. “Incredible utility ” is a conclusion, not a starting point for analysis under 35 U.S.C. 101. A conclusion that an asserted utility is incredible can be reached only after the Office has evaluated both the assertion of the applicant regarding utility and any evidentiary basis of that assertion. See MPEP 2107.01 and 2107.02.

8. The application describes preventive and curative treatment of alopecia (see paragraph [0039]). Further, the application describes a cosmetic treatment method to combat hair loss (see paragraph [0044]). The terms “prevent” and “combat” and “cure” are an absolute definition which means to stop from occurring and, thus, requires a higher standard than does “therapeutic” or “treat” or “alleviate”, especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies. The specification does not contemplate treatment. In terms of usefulness, the specification only recites prevention and cure of alopecia.

10. Dr. Leshin indicates there is no cure at present for alopecia; treatment is currently aimed at helping hair regrowth, but it cannot stop the spread of hair loss (see bottom of p. 2, [www.ds-health.com/derm.htm](http://www.ds-health.com/derm.htm)). The Australian government indicates that the most common cause of hair loss in men is androgenic alopecia, or male pattern baldness. The prior art indicates that while there are a number of treatments available for male pattern baldness, there is no cure. Treatments include minoxidil lotion and

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finasteride medication (see top of p. 2,

[http://betterhealthchannel.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Hair\\_loss?Open](http://betterhealthchannel.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Hair_loss?Open)).

WebMeds indicates that there is no “cure” for baldness. Treatments are available,

however, that help to slow hair loss and promote hair growth (see p. 3 of

[www.webmeds.us/hair-loss.html](http://www.webmeds.us/hair-loss.html)). Further,

[www.pennhealth.com/hairtransplant/type.html](http://www.pennhealth.com/hairtransplant/type.html) additionally indicates that there is no cure

for hair loss caused by androgenetic alopecia, although treatments are available. There

is no cure for hair loss caused by alopecia areata, not approved medications specifically

targeted to cure this disease (see p.1). The National Alopecia Areata Foundation (naaf)

further indicates that there is no cure for alopecia areata, but there are several available

treatments (see p. 3, [www.naaf.org/requestinfo/faq.asp](http://www.naaf.org/requestinfo/faq.asp)). All of the arts indicate that

there is no cure for hair loss and alopecia.

11. Therefore, there is no real world context. Given the teachings of the art as cited

above, one cannot conclude that a cure or a prevention of alopecia or hair loss exist.

Thus, a person of ordinary skill would consider the assertion of curing or preventing

alopecia to be “incredible in view of contemporary knowledge”. And the Applicant

cannot offer anything that would counter what contemporary knowledge might otherwise

suggest.

### ***Conclusion***

12. No claims are allowed.




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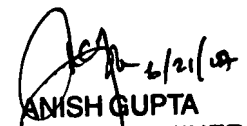
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982.

The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Julie Ha  
Patent Examiner  
AU 1654

  
ANSH GUPTA  
PRIMARY EXAMINER